DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

5 DEC 2016

MEMORANDUM FOR SGOG
ATTN: MAJ VALERIE G SAMS

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Multicenter Retrospective Study of Non-Compressible Torso Hemorrhage: Anatomic Locations of Bleeding and Comparison of Endovascular Versus Open Approach** presented at/published to **Eastern Association for the Surgery of Trauma Annual Scientific Assembly, FL, 10-14 Jan 2017** in accordance with MDWI 41-108, has been approved and assigned local file #**17007.**

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

PAUL T. BARNICOTT, GS-15-DAF
Deputy Director, Clinical Research Division

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
   a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D: Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]

   b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.

2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.

3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.

4. Attach a copy of your abstract, paper, poster and other supporting documentation.

5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.

6. On page 2, have either your unit commander, program director or immediate supervisor:
   a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.

7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.

8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.

9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.

10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.

11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

    For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

    If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

    If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

    If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

    If you are receiving an honorarium or payment for speaking a legal ethics review is required.

    If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement.
"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans.
"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP
"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	Valerie G. Sams, Maj, O4, 959 MDOS/SGOG	☐ YES ☒ NO	ISR H-15-004

5. PROTOCOL TITLE: (**NOTE:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)

Hemorrhage Control for Major Traumatic Vascular Injuries Phase I: A Retrospective Analysis of Non-Compressible Torso Hemorrhage

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

Multicenter retrospective study of non-compressible torso hemorrhage: anatomic locations of bleeding and comparison of endovascular versus

7. FUNDING RECEIVED FOR THIS STUDY? ☐ YES ☒ NO FUNDING SOURCE:

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
☐ YES ☒ NO **NOTE:** If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☐ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)

☐ 11b. PUBLISHED ABSTRACT (List intended journal.)

☐ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

☒ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)
Eastern Association for the Surgery of Trauma Annual Scientific Assembly, Florida, 10-14 January 2017

☐ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?
☐ YES ☒ NO ASSIGNED FILE # _____ DATE _____

13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE	
January 06, 2017	

14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	15. DUTY PHONE/PAGER NUMBER
Sams, Valerie G., valerie.g.sams.mil@mail.mil	916-3765/513-7957

16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Ronald Chang			University of Texas Health Sa
b. Erin E. Fox			University of Texas Health Sa
c. Thomas J. Greene			University of Texas Health Sa
d. Brian J. Eastridge, et al			University of Texas Health Sa
e. Valerie Sams	Maj	959 MDOS/SGOG	

17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? ☐ YES ☒ NO

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

18. AUTHOR'S PRINTED NAME, RANK, GRADE	19. AUTHOR'S SIGNATURE	20. DATE
Valerie G. Sams, Maj		November 29, 2016
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	**22. APPROVING AUTHORITY'S SIGNATURE**	**23. DATE**
Christopher E. White, COL		November 29, 2016

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED 2-Dec-2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17007
26. DATE REVIEWED 2 Dec 2016	27. DATE FORWARDED TO 502 ISG/JAC	

28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☑ NO ☐ YES If yes, give date. _____ ☐ N/A

29. COMMENTS ☑ APPROVED ☐ DISAPPROVED

IRB approved retrospective study with appropriate disclaimers

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	31. REVIEWER SIGNATURE	32. DATE
Kevin Kupferer/GS13/Hum Res Subj Prot Exp	KUPFERER.KEVIN.R.1086667270 Digitally signed by KUPFERER.KEVIN.R.1086667270 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=KUPFERER.KEVIN.R.1086667270 Date: 2016.12.02 10:09:34 -06'00'	2 Dec 2016

2nd ENDORSEMENT (502 ISG/JAC Use Only)

33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/PA

35. COMMENTS ☐ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	37. REVIEWER SIGNATURE	38. DATE

3rd ENDORSEMENT (59 MDW/PA Use Only)

39. DATE RECEIVED	40. DATE FORWARDED TO 59 MDW/SGVU
December 2, 2016	December 5, 2016

41. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	43. REVIEWER SIGNATURE	44. DATE
Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs	IINUMA.KEVIN.MITSUGU.1296227613 Digitally signed by IINUMA.KEVIN.MITSUGU.1296227613 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=IINUMA.KEVIN.MITSUGU.1296227613 Date: 2016.12.05 10:08:27 -06'00'	December 5, 2016

4th ENDORSEMENT (59 MDW/SGVU Use Only)

45. DATE RECEIVED	46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE

47. COMMENTS ☐ APPROVED ☐ DISAPPROVED

48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	50. DATE

DEPARTMENT OF THE ARMY
HEADQUARTERS, US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
810 SCHREIDER STREET
FORT DETRICK, MD 21702-5000

REPLY TO ATTENTION OF

MCMR-RPI

21 June 2015

MEMORANDUM FOR THE RECORD

SUBJECT: Initial Approval of the Protocol, "Hemorrhage Control for Major Traumatic Vascular Injuries Phase I: A Retrospective Analysis of Non-Compressible Torso Hemorrhage (NCTH)," Principal Investigator: LTC Kevin Chung, MC, US Army Institute of Surgical Research (USAISR), Joint Base San Antonio, Fort Sam Houston, TX, USAISR Protocol H-15-004, IRBNet ID 411591, Protocol Number M-10446, in Support of the Proposal "Hemorrhage Control for Major Traumatic Vascular Injuries," Proposal Principal Investigator: John Holcomb, MD, University of Texas Health Science Center, Houston, Proposal Number 13057176, Award Number W81XWH-14-1-0112

1. The Headquarters, US Army Medical Research and Materiel Command Institutional Review Board (HQ USAMRMC IRB) reviewed the above-referenced research protocol for compliance with applicable human subject protection regulations. There are no outstanding human research protections issues.

2. In accordance with 32 CFR 219.110(a,b), the research qualifies for review via an expedited review procedure as it involves no more than minimal risk and is included in the categories of research listed in the 9 November 1998 Notice in the Federal Register (63 FR 60364-60367), specifically, research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (Category 5).

3. The research protocol is approved for a one-year period, 21 June 2015 – 20 June 2016 pending approval of the Commander, USAISR.

4. The study is approved to review medical record data from AHLTA, Healthcare Artifact and Image Management Solution, CHCS, San Antonio Military Medical Center Trauma Registry, and Essentris databases for patients with non-compressible torso hemorrhage between January 2008 and December 2012.

5. The requirement to obtain informed consent is waived as allowed under 32 CFR 219.116(d) as the research involves no more than minimal risk to the subjects, the waiver will not adversely affect the rights and welfare of the subjects, and the research could not practicably be carried without the waiver.

6. A waiver of the Health Insurance Portability and Accountability Act Privacy Rule requirement to obtain authorization for the use and disclosure of protected health information in research is approved as allowed under DOD 6025.18-R, C7.9.2.2.

7. Approved documents:

a. Core Protocol (NCTH Protocol Version 3, dated 13 February 2015);

MCMR-RPI
SUBJECT: Initial Approval of the Protocol, "Hemorrhage Control for Major Traumatic Vascular Injuries Phase I: A Retrospective Analysis of Non-Compressible Torso Hemorrhage (NCTH)," Principal Investigator: LTC Kevin Chung, MC, US Army Institute of Surgical Research (USAISR), Joint Base San Antonio, Fort Sam Houston, TX, USAISR Protocol H-15-004, IRBNet ID 411591, Protocol Number M-10446, in Support of the Proposal " Hemorrhage Control for Major Traumatic Vascular Injuries," Proposal Principal Investigator: John Holcomb, MD, University of Texas Health Science Center, Houston, Proposal Number 13057176, Award Number W81XWH-14-1-0112

b. Site-specific Protocol (Version 1, dated 11 May 2015); and

c. Manual of Operations (NCTH MOO Version 3, dated 3/9/15).

8. Please note the following requirements:

a. Submit all proposed changes to the study for review and approval by the HQ USAMRMC IRB before initiating the changes.

b. Promptly report to the HQ USAMRMC IRB:

(1) All unanticipated problems involving risks to subjects or others and related serious adverse events.

(2) Any protocol deviation that affects subjects' safety or rights and/or the integrity of the study.

c. Submit a continuation report, a copy of the current protocol and supporting documents to the HQ USAMRMC IRB in sufficient time to ensure review and approval on or before 20 June 2016.

d. Submit a final study report and request to close the protocol upon completion of all research activities.

9. The IRB Office point of contact for this action is Debra DePaul, RN, MSN, General Dynamics Information Technology Corporation, at 301-619-2620 or debra.depaul.ctr@mail.mil.

LTC JAY R. BUCCI, MC
Chair
Headquarters, US Army Medical Research
and Materiel Command
Institutional Review Board

Multicenter retrospective study of non-compressible torso hemorrhage: anatomic locations of bleeding and comparison of endovascular versus open approach

Chang R, Fox EE, Greene TJ, Eastridge BJ, Gilani R, Chung KK, DeSantis SM, DuBose JJ, Tomasek JS, Fortuna GR, Sams VG, Todd SR, Podbielski JM, Wade CE, Holcomb JB

Objective: To describe the anatomic location of truncal bleeding in patients presenting with non-compressible torso hemorrhage (NCTH) and to compare endovascular (ENDO) versus open (OPEN) management.

Methods: Retrospective study of adult trauma patients with NCTH admitted to 4 urban level 1 trauma centers in 2008-2012. Inclusion criteria: NCTH defined as named axial torso vessel disruption, AIS chest or abdomen ≥3 with shock (base excess <-4) or operation in ≤90 minutes, or pelvic fracture with ring disruption. Exclusion criteria included isolated hip fractures and falls from standing. After dividing patients into ENDO and OPEN groups based on the initial approach to control NCTH, a purposeful multivariate logistic regression model was used to test the hypothesis that ENDO was associated with reduced in-hospital mortality in NCTH patients.

Results: 560 patients with NCTH underwent ENDO (n=175, 31%) or OPEN (n=385, 69%). ENDO patients had more blunt trauma (95% vs 32%, $p<0.01$); were more severely injured (median ISS 34 vs 25, $p<0.01$); had increased time to intervention (median 295 vs 87 min, $p<0.01$); and had lower mortality (17% vs 31%, $p<0.01$) compared to OPEN. ED vital signs and presence of shock were similar ($p>0.05$). ENDO was used for a narrow range of vascular injuries, while OPEN injuries were more diverse (Table). Use of ENDO for NCTH increased from 23% in 2008 to 39% in 2012. After adjusting for age, mechanism, ISS, use of REBOA, and admission SBP, base excess, and platelet count, multivariate logistic regression found that ENDO was associated with decreased mortality compared to OPEN (OR 0.38, 95% CI 0.19 – 0.77).

Conclusion: ENDO was used in a relatively narrow range of bleeding control indications in this NCTH population. Although ENDO may reduce mortality in NCTH patients, significant group differences limit the generalizability of this finding.

Table. Anatomic location of NCTH

	ENDO (n=175)			OPEN (n=385)	
Ascending aorta, arch, and arch vessels	7	4.0%		33	8.6%
Superior vena cava	0	0.0%		14	3.6%
Internal thoracic arteries	0	0.0%		19	4.9%
Descending aorta	44	25.1%		16	4.2%
Pulmonary vessels	0	0.0%		10	2.6%
Abdominal aorta	2	1.1%		17	4.4%
Common hepatic & splenic arteries	14	8.0%		16	4.2%
Other abdominal visceral arteries	8	4.6%		49	12.7%
Abdominal visceral veins	2	1.1%		33	8.6%
Inferior vena cava	0	0.0%		56	14.5%
Renal arteries	14	8.0%		10	2.6%
Renal veins	0	0.0%		8	2.1%
Common & external iliac arteries	5	2.9%		24	6.2%
Internal iliac arteries & branches	73	41.7%		34	8.8%
Common, external, & internal iliac veins	3	1.7%		32	8.3%
Unknown/other	3	1.7%		14	3.6%

16-153 Sheep #199

Blood smears: Marked polychromasia with anisocytosis (macrocytic erythrocytes), metarubricytosis and basophilic stippling and bands consistent with an appropriate regenerative anemia in this case as this patient was markedly anemic.